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Date

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## URGENT FIELD SAFETY NOTICE

## NOTIFICATION ABOUT A VOLUNTARY RECALL

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### **Affected Products:**

Arthrex Power System 600, Sagittal Saw Blades

#### **Part no. / Lot no.:**

AR-600-003S / LOT 256184 (size 90 x 25.4 x 1.0 mm)

AR-600-004S / LOT 255271 (size 90 x 25.4 x 1.19 mm)

AR-600-005S / LOT 257336 (size 90 x 25.4 x 1.27 mm)

AR-600-006S / LOT 260902 (size 90 x 25.4 x 1.47 mm)

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Dear Sir and Madam,

Arthrex would like to inform you that the above named products were labeled with "use by" date 2018-11 instead of **2018-10** on outer box label. The inner label (patient label) shows the correct date 2018-10.

### **Potential hazards and consequences when using the sawblades after 2018-10**

- Expiration date check is done by outer packaging. The difference to inner label date is unnoticed. Patient is treated with a sawblade which exceeds expiration date. The maximum time deviation is 1 month.
- Deviation is realized not until surgery begins. The sawblade will be used beyond expiration date 2018-10. The patient will be treated with a sawblade which expiration exceeded.
- Deviation is realized not until surgery begins. A replacement sawblade is available. Operating theatre member is getting a new blade which expiration date is not exceeded. Delay of surgery not longer than 30 minutes.
- Deviation is realized not until surgery begins. A replacement sawblade is not available. The sawblade will be re-sterilized and used. The additional hospital sterilization does not compromise instruments performance. Delay of surgery not longer than 30 minutes.

Despite the product is in accordance to its manufacturing specification the labeling can be misleading. Therefore Arthrex decided to conduct a voluntary recall of the above named part and lot numbers of Arthrex Sagittal Sawblades for Arthrex handpiece AR-600.

Actions Required:  
Recall / Exchange

Immediate Actions:

- If you have one or more of the affected products on stock please return to Arthrex GmbH.
- The exchange of affected lots is at no charge. In case of questions for replacement please contact your sales representative or customer service.
- We kindly ask you to return the response letter for documentation purpose of recall, also in case no devices are left in your stock.  
**Please send the filled form to:**  
**Contact Adress Distributor/Subsidiary**
- Please make sure that this notice is distributed to all affected departments in your facility. In case the devices have been provided to other parties please forward this information.
- The competent authority in your country has been notified about this safety information.

We apologize for possible inconveniences accompanying with this action and thank you for your support our mission „Helping Surgeons Treat Their Patients Better“.

Please do not hesitate to contact us for further information.

Best regards

**ARTHREX GMBH**

i.A. Julia Hoyer  
Team Manager Quality & Regulatory Affairs Engineering

## Arthrex customer's response form Field safety notice, voluntary recall

**Please mark the appropriate box with an "x":**

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The products in question of the field safety notice are not on our stock anymore.

AR-600-003S Lot 256184  
AR-600-004S Lot 255271  
AR-600-005S Lot 257336  
AR-600-006S Lot 260902

☐

We are returning the following products (please specify quantity) to the address below

Part no.	Lot	Quantity
AR-600-003S	256184	
AR-600-004S	255271	
AR-600-005S	257336	
AR-600-006S	260902	

☐

The following parts are on stock:

Part no.	Lot	Quantity
AR-600-003S	256184	
AR-600-004S	255271	
AR-600-005S	257336	
AR-600-006S	260902	

We registered this field safety notice but will not return the products. Hereby we confirm not to use the devices beyond 31.10.2018.

\_\_\_\_\_  
Facility Name

\_\_\_\_\_  
Signature and Date

\_\_\_\_\_  
Name and Title (block letters)

Return to:

Please insert address of distributor  
/subsidiary